



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

REGION IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

JUN 28 2007

Report Number: A-04-05-03002

Michael Grable, M.D., President
Atlantic Urological Associates, P.A.
545 Health Boulevard
Daytona Beach, Florida 32114

Dear Dr. Grable:

Enclosed are two copies of the Department of Health and Human Services, Office of Inspector General (OIG) final report entitled "Audit of Pathology Laboratory Services Claimed by Atlantic Urological Associates, P.A. for Calendar Year 2004." The audit objectives were to determine whether the Practice claimed reimbursement for pathology laboratory services in accordance with Medicare Part B medical necessity and documentation requirements during calendar year 2004 and to analyze the Practice's utilization patterns for pathology services.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR part 5.) As such, within 10 business days after the final report is issued, it will be posted on the Internet at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call John Drake, Audit Manager, at (404) 562-7755. Please refer to report number A-04-05-03002 in all correspondence.

Sincerely,

A handwritten signature in blue ink that reads "Peter J. Barbera".

Peter J. Barbera
Regional Inspector General
for Audit Services, Region IV

Enclosures

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF PATHOLOGY
LABORATORY SERVICES
CLAIMED BY ATLANTIC
UROLOGICAL ASSOCIATES, P.A.
FOR CALENDAR YEAR 2004**



Daniel R. Levinson
Inspector General

June 2007
A-04-05-03002

Office of Inspector General

<http://oig.hhs.gov>

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OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Congress established Medicare under Title XVIII of the Social Security Act to provide health insurance coverage to people age 65 and over, the disabled, and people with end-stage renal disease. The Medicare program pays for expenses incurred for items or services that are reasonable and necessary for the diagnosis or treatment of illness or injury.

Sections 1833 and 1861 of the Social Security Act provide for payment of clinical diagnostic laboratory services, including pathology services, under Medicare Part B. The services must be ordered either by a physician or a qualified non-physician practitioner and may be furnished by certain entities including hospitals, skilled nursing facilities, and laboratories. A laboratory performing tests on human specimens must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988.

The Medicare program reimburses Medicare entities for pathology services based on the number of biopsies examined. Biopsies are excised tissue packaged and sent to a pathologist for a microscopic examination. Each tissue examination is billed as one unit of service, and each is reimbursed equally within the same Current Procedural Terminology (CPT) code. The majority of pathology services reviewed in this audit were billed under CPT code 88305, "Level IV – Surgical pathology, gross and microscopic examination, Prostate, Needle Biopsy."

Atlantic Urological Associates, P.A. (the Practice) is a physicians' group practice located in Daytona Beach, Florida, that provides urology services related to urinary infections, incontinence, kidney stones, infertility, bladder cancer, vasectomies, and prostate cancer. In 2003, the Practice contracted with a pathologist to provide pathology services on behalf of its patients. In July 2003, the Practice contracted with a management company to oversee the daily operations of its clinical laboratory, with responsibilities that included securing rental space, hiring non-physician personnel, purchasing laboratory supplies, and assisting in ordering furniture and equipment. The Practice's laboratory was one of 13 laboratories the management company operated within the same office building. The Practice's laboratory contained its own equipment and was in a separate room within this office building.

Through its contractual arrangements, the Practice received Medicare reimbursement totaling \$378,154 during calendar year (CY) 2004 for pathology services performed at its laboratory in Leesburg, Florida. We contracted with a Medicare Program Safeguard Contractor (PSC) to review the Practice's medical records for a random sample of 100 paid claims during this period to determine whether pathology services provided were reasonable, medically necessary, and supported by adequate documentation.

OBJECTIVES

Our audit objectives were:

- to determine whether the Practice claimed reimbursement for pathology laboratory services in accordance with Medicare Part B medical necessity and documentation requirements during CY 2004 and
- to analyze the Practice's utilization patterns for pathology services.

RESULTS OF REVIEW

During our audit period, the Medicare program had not created any national or local coverage determinations or standards for the number of tissue samples that should be examined for urology patients with primarily prostate-related diagnoses. In the absence of these standards, the PSC medical reviewer determined that the Practice's claims for pathology laboratory services generally complied with Medicare Part B medical necessity and documentation requirements. The PSC stated that sufficient documentation existed for each of the sampled claims to indicate that the services billed to Medicare were actually provided. The PSC also stated that the medical necessity for a biopsy procedure could be established, within the realm of professional judgment, for 96 of the 100 sampled claims. For four of the sampled claims, the PSC concluded that the medical need for a biopsy was not established, but it could not definitively rule out the appropriateness of a biopsy. The PSC also had concerns about the volume of tissue samples taken in an additional three sampled claims. Because the Medicare program has not created any national standards or local coverage determinations for the number of tissue samples that are to be obtained or reimbursed on a single day, we elected not to question the Medicare payment for these seven claims.

We noted an increase in the number of pathology services requested and performed after the Practice contracted with a laboratory management company. In CY 2002, prior to the first full year of the Practice's contractual laboratory arrangement, the Practice's physicians requested from independent laboratories an average of seven tissue examinations per claim. In CY 2004, after completing the contractual arrangements for its laboratory operations, the Practice's physicians requested an average of nine tissue examinations per claim. In addition, the Medicare carrier, First Coast Service Options, Inc. (FCSO) reimbursed the Practice for more units of service of CPT 88305, on average, than it reimbursed other providers for CPT 88305.

The Practice acknowledged that its utilization increased and explained the increase by noting that industry standards were evolving. The Practice stated that it had increased the number of tissue examination requests from earlier years in an attempt to more fully meet the needs of its patients.

This report contains no recommendations.

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INTRODUCTION

BACKGROUND

Medicare Overview

Congress established Medicare under Title XVIII of the Social Security Act to provide health insurance coverage to people age 65 and over, the disabled, and people with end-stage renal disease. The Medicare program pays for expenses incurred for items or services that are reasonable and necessary for the diagnosis or treatment of illness or injury.

Medicare Part B reimburses for physician services, outpatient hospital services, medical equipment, supplies and clinical laboratory services. Within the Department of Health and Human Services, the Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Anatomical Pathology Laboratory Services

Sections 1833 and 1861 of the Social Security Act provide for payment of clinical diagnostic laboratory services, including pathology services, under Medicare Part B. The services must be ordered either by a physician, as described in 42 CFR § 410.32(a), or by a qualified non-physician practitioner, as described in 42 CFR § 410.32(a)(3), and may be furnished by any of the entities identified in 42 CFR § 410.32(d)(1), including hospitals, skilled nursing facilities, and laboratories. A laboratory seeking Medicare reimbursement for performing tests on human specimens must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988, as set forth at 42 CFR part 493.

The Medicare program reimburses for pathology services based on the number of biopsies examined. Biopsies are excised tissue packaged and sent to a pathologist for a microscopic examination. Each tissue examination is billed as one unit of service, and each is reimbursed equally within the same Current Procedural Terminology (CPT) code. The majority of pathology services reviewed in this audit were billed under CPT code 88305, “Level IV – Surgical pathology, gross and microscopic examination, Prostate, Needle Biopsy”.

Atlantic Urological Associates, P.A.

Atlantic Urological Associates, P.A. (the Practice) is a physicians’ group practice licensed in the State of Florida. As of December 31, 2004, the Practice employed 16 physicians and 1 physician’s assistant. The Practice’s specialty is urology – the medical subspecialty that covers the diagnosis, surgical and medical treatment of diseases of the kidney, bladder, prostate and reproductive systems of males, and the urinary tract of females. The Practice has nine offices where patients are seen, including its main office in Daytona Beach, Florida. The Practice also maintains a central billing office through which all claims are processed.

In 2003, the Practice contracted with a pathologist to provide services on behalf of both Medicare and non-Medicare patients through an in-office laboratory. In July 2003, the Practice contracted with a management company to oversee the daily operations of its clinical laboratory, with responsibilities that included securing rental space, hiring non-physician personnel, purchasing laboratory supplies, and assisting in ordering furniture and equipment. The Practice's laboratory was one of 13 laboratories the management company operated within the same office building. The Practice's laboratory contained its own equipment and was in a separate room within this office building. The laboratory is located in Leesburg, Florida, approximately 71 miles from the Practice's main office. The contracted pathologist serves as the laboratory's director. The State of Florida conducted a licensure survey of the Practice's laboratory in January 2003, and renewed the laboratory's certificate on October 30, 2003, expanding the testing specialties of the laboratory to bacteriology, routine chemistry, and endocrinology, in addition to the previous certifications for histopathology and cytology. The Clinical Laboratory certificate for the Practice's laboratory was renewed effective April 4, 2004, for the performance of tests related to bacteriology, cytology, endocrinology, histopathology, and routine chemistry.

The Practice received \$378,154 in Medicare reimbursement for 590 claims for pathology services performed during calendar year (CY) 2004 through the contractual arrangements at its Leesburg, Florida laboratory. Prior to the contractual arrangements and establishing its laboratory, the Practice ordered these services from independent laboratories. First Coast Service Options, Inc. (FCSO) processed the Medicare claims for the Practice.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our audit objectives were:

- to determine whether the Practice claimed reimbursement for pathology laboratory services in accordance with Medicare Part B medical necessity and documentation requirements during CY 2004 and
- to analyze the Practice's utilization patterns for pathology services.

Scope

We selected a random sample of 100 Medicare claims totaling \$70,970 that FSCO paid during the CY 2004. We provided the associated medical records to the Program Safeguard Contractor (PSC) for medical review to ensure the pathology services billed for were reasonable, necessary, and in accordance with Medicare Part B requirements.

Our review of internal controls was limited to understanding the Practice's patient biopsy process, labeling and recording of biopsy tissue for shipment to its Leesburg laboratory, receipting and recording of tissue at the Leesburg laboratory, laboratory processing, bill processing, and receipting of Medicare payments.

We conducted our fieldwork at the Practice's office in Daytona Beach and its laboratory in Leesburg, Florida.

Methodology

To accomplish our objectives, we:

- reviewed applicable provisions of the Social Security Act, Code of Federal Regulations, and the Provider Reimbursement Manual;
- interviewed staff at the Practice's office and laboratory and gained an understanding of the procedures the Practice used at its office and laboratory;
- reviewed various contractual documentation regarding arrangements for laboratory services, including the employment of the contracted pathologist, rental of space, and management operations;
- identified and reviewed a sample of 100 claims that FCSO paid for the Practice's pathology services during CY 2004, to verify compliance with Medicare regulations, and calculated the average number of tissue samples per claim of CPT 88305 that the Practice examined;
- contracted with a PSC to review the Practice's medical records for the 100 claims to determine if pathology services were medically necessary, adequately documented, and performed at the level indicated on the claim;
- identified claims containing units of CPT 88305 that FCSO paid to independent laboratories that the Practice used during CY 2002;
- identified claims containing units of CPT 88305 that FCSO reimbursed to all other providers during CY 2004; and
- compared¹ the Practice's average units per claim of CPT 88305 before and after it contracted with a laboratory management company, and compared the Practice's average units per claim of CPT 88305 after it opened its own laboratory to the average units per claim of CPT 88305 that FCSO paid to all other providers.

We performed our review in accordance with generally accepted government auditing standards.

RESULTS OF REVIEW

¹ We limited the claims that were compared to those that contained a diagnosis code the Practice billed during CY 2004 and with a place of service code of 11 or 81 ("in-office" or "independent laboratory," respectively).

During our audit period, the Medicare program had not created any national or local coverage determinations or standards for the number of tissue samples that should be examined for urology patients with primarily prostate-related diagnoses. In the absence of these standards, the PSC medical reviewer determined that the Practice's claims for pathology laboratory services generally complied with Medicare Part B medical necessity and documentation requirements. The PSC stated that sufficient documentation existed for each of the sampled claims to indicate that the services billed to Medicare were actually provided. The PSC also stated that the medical necessity for a biopsy procedure could be established, within the realm of professional judgment, for 96 of the 100 sampled claims. For four of the sampled claims, the PSC concluded that the medical need for a biopsy was not established, but it could not definitively rule out the appropriateness of a biopsy. The PSC also had concerns about the volume of tissue samples taken in an additional three sampled claims. Because the Medicare program has not created any national standards or local coverage determinations for the number of tissue samples that are to be obtained or reimbursed on a single day, we elected not to question the Medicare payment for these seven claims.

We noted an increase in the number of pathology services requested and performed after the Practice opened its own laboratory. In addition, as shown below, FCSO reimbursed the Practice for more units per claim of CPT 88305, on average, than it reimbursed other providers for CPT 88305.

Average units of CPT 88305 requested <i>before</i> opening its own laboratory and claiming reimbursement for services	7.09
Average units of CPT 88305 requested <i>after</i> opening its own laboratory and claiming reimbursement for services	8.90
Average units of CPT 88305 FCSO paid to all other providers	5.40

The Practice acknowledged that its utilization increased and explained the increase by noting that industry standards were evolving. The Practice stated that it had increased the number of tissue examination requests from earlier years in an attempt to more fully meet the needs of its patients. The Practice provided some industry literature in support of its contention that an increased number of tissue examinations may improve patient outcomes.

This report contains no recommendations.